



This document is scheduled to be published in the Federal Register on 03/28/2013 and available online at <http://federalregister.gov/a/2013-07166>, and on [FDsys.gov](http://FDsys.gov)

**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Start-Up Exclusive License:** Photosensitizing Antibody-Fluorophore Conjugates for Photoimmunotherapy

**AGENCY:** National Institutes of Health, Public Health Service, HHS

**ACTION:** Notice

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a worldwide exclusive patent license, to practice the inventions embodied in PCT patent application PCT/US2012/044421, filed June 27, 2012 (HHS Reference# E-205-2010/2-PCT-01), which is a continuation-in-part of U.S. Application No. 13/180,111 (E-205-2010/1-US-01) which claims priority to U.S. provisional application No. 61/363,079 (E-205-2010/0-US-01), and entitled “Photosensitizing Antibody-Fluorophore Conjugates,” to Aspyrian Therapeutics, Inc., a company incorporated under the laws of the State of Delaware, having its headquarters in San Diego, California.

The United States of America is the assignee of the rights of the above invention.

The field of use may be limited to “use of photosensitizing antibody-fluorophore conjugate by itself for Photoimmunotherapy (PIT), or in combination with cancer therapeutic agents, to treat cancer or pre-cancerous hyperplasia”, and may be further limited to certain types of cancer and/or specific platforms.

The license will include the priority case US 13/180,111, which is currently licensed to Aspyrian under an exclusive evaluation option license. The exclusive commercialization license proposed in this notice will supersede and replace the exclusive evaluation option license.

**DATE:** Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before [Insert date fifteen (15) days from date of publication of notice in the FEDERAL REGISTER] will be considered.

**ADDRESS:** Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Uri Reichman, Ph.D., M.B.A, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4616; Facsimile: (301) 402-0220; E-mail: [Reichmau@mail.nih.gov](mailto:Reichmau@mail.nih.gov). A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

**SUPPLEMENTARY INFORMATION:** The invention is in the field of Photoimmunotherapy (PIT). More specifically, the invention relates to antibody-fluorophore conjugates where the antibody is specific for cancer cells and the fluorophore is IR700 dye. Binding of such conjugates to targeted cancer cells followed by irradiation with near infrared light (NIR) was shown to kill cancer cells in a highly specific manner. Furthermore, the invention discloses that the therapeutic effect of the PIT conjugate is significantly enhanced by the administration of one or more anti-cancer agents following the irradiation step. This is achieved by the markedly rapid accumulation of the therapeutic agent in the PIT-treated tissue. Also provided in the invention are wearable devices that incorporate NIR light emitting diodes (LEDs) and can be used to activate the PIT conjugates.

The prospective exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

March 22, 2013  
Date

---

Richard U. Rodriguez,  
Director  
Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

[FR Doc. 2013-07166 Filed 03/27/2013 at 8:45 am; Publication Date: 03/28/2013]